

The National Institute of Standards and Technology within the U.S. Department of Commerce recently proposed a rule to codify the long-standing interpretation of the Bayh-Dole Act’s march-in right: that the provision cannot be used as a government price control mechanism when a federally-funded invention has been successfully commercialized. Experts from across the university, technology transfer, venture capital, biopharmaceutical, and public policy sectors endorsed NIST’s proposed rule change, saying that it was a welcome reinforcement of a four-decades-old interpretation of the Bayh-Dole Act.

“Any assertion that pricing can or should be used as a basis for exercising march-in rights on a product developed, commercialized and sold by our licensees and sublicensees is inconsistent with both the letter and the spirit of the Bayh-Dole Act. Moreover, it could have devastating consequences to this country’s leadership position in basic and applied research and its long history of success in commercializing university discoveries.” – **Stephen Susalka, AUTM**

Endorsed by officials from Duke University, Tulane University, Vanderbilt University, University of Rhode Island, Oregon State University, University of Hawai’i, University of Notre Dame, University of Arizona, University of Pittsburgh, University of Michigan, University of New Hampshire, Lankenau Institute for Medical Research, Oregon Health & Science University, Cold Spring Harbor Laboratory, UWM Research Foundation, AURP, UNeMed, Fuentek, Dana-Farber Cancer Institute, U.S. Chamber of Commerce

“If policymakers reinterpret the law to allow price controls, they will undermine its purpose and end our odyssey of innovation. Fortunately, the NIST proposal would codify and clarify the law’s intent, extending our successful trajectory into the future.” – **AUTM Past Presidents and Chairs (1986-2021)**

“If the Bayh-Dole Act march-in provision is used to control drug prices, it may also lead to proposals to control prices of other products developed through federal government research. Such policies would potentially impact not only the pharmaceutical sector, but also life sciences, environmental sciences, computer sciences, engineering, automotive, and an almost endless array of inventions that could significantly benefit those, and other, industry sectors. Clearly, this could have a chilling impact on American innovation, the exact opposite of the Bayh-Dole Act’s intended purpose.” – **Patrick Kilbride, U.S. Chamber of Commerce**

“The changes and clarifications made by NIST’s proposed rule continue to support the entrepreneur’s participation in federal funding projects and work – through streamlining, improved accountability, and through re-affirmation around the issue of march-in rights – that is, the government’s march-in authority is not intended to set prices on resulting products.” – **Karen Kerrigan, Small Business & Entrepreneurship Council**

“Using the march-in right as a price control mechanism will create unacceptable risk for companies and will impair investment in and development of Subject Inventions, and thereby goes well beyond the original intent and undermines the goals of the Bayh-Dole Act.” – **Benjamin Dibling, Jennifer Langenberger, Penn Center for Innovation**

“Price should not be a factor in considering the exercise of march-in rights under the Bayh-Dole Act. The original authors and sponsors of the legislation added a march-in provision to the act to ensure the successful licensing of an invention. The language has no bearing on the consumer market for that invention. This was true of the original intent of Congress and has continued to be true over more than forty years of widespread practice between technology transfer professionals and federal funding agencies.” – **Erik Iverson, Michael Falk, Stephanie Adamany, Wisconsin Alumni Research Foundation**

“If Bayh-Dole were reinterpreted to construe its language the way that consumer advocates are requesting, it would add a layer of uncertainty to an already high-risk endeavor that few if any investors would find acceptable. It is simply not reasonable to expect the private sector to continue investing multiple millions of dollars and years of dedicated and focused effort if the end product is to be saddled with the potential of governmental pricing demands that will be driven largely by political considerations.” – **Robert P. Taylor, Alliance of U.S. Startups and Inventors for Jobs**

“Expanding March-in rights to include price control will create an environment of uncertainty and mistrust between academia and industry and lead to many federally funded inventions sitting on the shelf just like the days before Bayh-Dole. In addition, I also support removing the words “exclusively” and “of the contractor” from the current language so that the intent is clear.” – **Michael Dixon, UNeMed**

“The inclusion of march-in rights, as written in Bayh-Dole, were intended to ensure good faith efforts from the industry, including the health care industry, to encourage commercialization of inventions that were federally funded. Unfortunately, a skewed interpretation has recently been proposed of the rule, wrongly utilizing march-in as an avenue to control drug prices by forfeiting IP rights.” – **John Stanford, Incubate Coalition**

“Bayh-Dole has yielded tremendous practical benefits. But injecting “pricing” considerations into march-in regulations would place these benefits of practical usage for taxpayers and society at great risk.” – **Andrew L. Schlafly, Eagle Forum Education and Legal Defense Fund**

“Price control was never contemplated as an effective economic incentive by the framers of Bayh-Dole, and to our understanding, this position has been consistently supported in rulings over the years. Furthermore, the mechanism of using Bayh-Dole to control prices would entail a threat that the federal government eliminate the right to elect title with rights vesting in the government after the product has been successfully commercialized. As such, price control and the threat of IP rights vesting back to the government are not consistent with the intent of Bayh-Dole law, which is to create economic incentives.” – **Esther Kashkin, K2 Biotechnology Ventures**

“Full implementation of the proposed rule will provide clarity and certainty to the rights granted under Bayh-Dole and will give private companies confidence to invest and turn their publicly funded ideas into tangible products that better American lives.” – **Ginevra Joyce-Myers, Center for Innovation and Free Enterprise**

“Weakening the certainty of access to IP rights provided under Bayh-Dole by employing march-in to address drug pricing issues – especially if it meant a government entity could walk in and retroactively commandeer innovations private-sector enterprises invested hundreds of millions, if not billions, to create – would significantly diminish private businesses’ incentives to commercialize products supported by federally funded research.” – **Stephen Ezell, Information Technology and Innovation Foundation**

“Further evidence that Bayh-Dole march-in is not legally permissible nor available as a price control mechanism is the fact that both Democratic and Republican administrations have consistently declined to invoke it in connection with price. They have refused to legitimize numerous petitions over many years seeking march-in based on a product’s price. Bipartisan officials have appropriately denied every such petition that advanced a false theory, properly finding no basis in the law.” – **James Edwards, Conservatives for Property Rights**

“The argument has been made that March-In Rights outlined in the Bayh-Dole Act can be interpreted to help control drug prices in the US. Senators Bayh and Dole refuted this interpretation and also confirmed the proper interpretation years ago. Once I saw this, I realized that the ‘control drug prices’ was a ridiculous interpretation. While the idea of controlling drugs as part of restraining US healthcare costs is a good thing, the use of the March-In Rights for that purpose is not.” – **John A. Fraser, Burnside Development and Associates**

“I can say with certainty that it was never our intention that the government could march-in against a successfully developed Bayh-Dole invention because someone didn’t like its price. Such an interpretation is bad law and even worse public policy. It would have devastating consequences on public welfare.” – **Joseph Allen, Bayh-Dole Coalition**

“Those who seek government intervention because they believe markets should operate differently are free to invoke other, more suitable laws designed to protect the interests of consumers or competitors, or that regulate products or markets for such products. The Bayh-Dole Act’s march-in provisions, on the other hand, are designed to cure specific instances of noncompliance or omissions by specific actors, not to regulate markets or to set the commercial terms under which products are marketed, priced, or sold.” – [Hans Sauer, Biotechnology Innovation Organization](#)

“The proposed regulation achieves this important clarification of the march-in power by codifying in its enacting regulations the meaning of the statutory text and its longstanding interpretation by federal officials that it is not a price-control provision.” – [Adam Mossoff, Hudson Institute, George Mason University, Antonin Scalia Law School](#)

“While use of Bayh-Dole’s march-in rights to regulate prices might potentially lower the cost of a drug in the short term, over the long term it would kill the proverbial goose that laid the golden egg, resulting in less investment in lifesaving pharmaceutical innovation, and in particular less investment in the development and commercialization of pharmaceutical innovation arising out of federally funded research, along with less collaboration between the private and public sectors.” – [Chris Holman, Center for the Protection of Intellectual Property, George Mason University, Antonin Scalia Law School](#)

“Using price as a basis for exercising march-in rights, could cause private sector entities to avoid licensing of federally funded intellectual property (IP) from universities, which could endanger their broader IP portfolios. Licensing early-stage technologies from university research requires extensive additional research and product development and may implicate other patent holders and IP rights by the time a product reaches the market. Bayh-Dole’s march-in provision was not intended to implicate IP owned or controlled by private industry that was not created with federal support.” – [DeChane L. Dorsey, AdvaMed Accel](#)

“Bayh-Dole’s limited purpose march-in provision should not be expanded beyond Congress’s intent, and certainly not in a way that will undermine innovation and diminish valuable public-private partnerships. Such partnerships depend on the sanctity of contracts whereby rights in publicly funded research are exchanged for value to promote the development of that research into useful products for the public benefit. If the private sector cannot rely on those agreements, the essential work required to develop basic science into useful products will not occur.” – [Brian O’Shaughnessy, LES USA & Canada](#)

“There is simply no textual or logical basis for advocating march-in actions under Bayh-Dole on the basis of market prices. The Proposed Rule formally codifies the text and intent of Bayh-Dole that march-in rights cannot be used as a means to impose drug price controls.” – [Timothy H. Lee, Jeffrey L. Mazzella, Center for Individual Freedom](#)

“There is no authorization in the Act for funding agencies to impose downstream ex post price controls on contractors or their licensees. While this regulatory clarification should not be needed—given the definitive debunking of Arno & Davis et al.—it is clear that the claims will continue to be advanced. Accordingly, a clear rulemaking by NIST is a crucial first step in rebutting these initiatives.” – [Sean M. O’Connor, Center for the Protection of Intellectual Property](#)

“NIST’s proposed revisions would reaffirm the longstanding intent of the government’s “march-in rights” under the Bayh-Dole Act which has been the key to this country’s global leadership in innovation. Georgia Bio believes that deviation from the plain language of the statute and the clear intent of Congress would threaten this country’s successful public-private partnership in numerous technical fields including the life sciences. The Bayh-Dole Act has been called “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century.” The proposed regulations must continue that record of success.” – [Maria Thacker-Goethe, Georgia Bio](#)

“Although march-in has never been utilized, the existence of a scheme by which federal agencies can implement price controls on particular products should not be accepted. This proposed rule would finally make it clear that the federal government has no jurisdiction to implement price controls under the Bayh-Dole Act.” – [Adam Brandon, Beverly McKittrick, FreedomWorks Foundation](#)

“Implementing this rule will preserve the original intent of the Bayh-Dole Act to ensure exclusive patent rights to the universities, small businesses, and non-profit researchers who rely on federal grants. This promise will ensure the ongoing success of public-private partnerships in the United States and promote the creation of breakthrough innovations that improve American lives.” – **Kent Kaiser, Trade Alliance to Promote Prosperity**

“Short-run or short-sighted public policy is almost always bad long-run economics – and in this case short-sighted politics could also mean bad long-run public health. The problem is that we are almost sure to face another COVID-like pandemic. And, when we face that pandemic if “March In” was exercised due to price it will be obvious to all of the companies involved that racing to solve the next problem isn’t worth the risk or the money.” – **Charles Sauer, Market Institute**

“Increasingly, we see research collaborations as a critical way to make the biggest scientific advances in the most rapid ways possible. For this reason, we are strong supporters of The Bayh-Dole Act. Good ideas can happen in any aspect of the pharmaceutical research chain, be that in the public sector, universities, the National Institutes of Health, and in private sector industry. Lilly wants to incentivize all these individuals to work together to bring their best ideas to the table and leverage each individual member of the sectors’ strengths to create the greatest number of possibilities for bringing treatments to patients. The Bayh-Dole Act provides incentives to support this vision.” – **Shawn O’Neil, Eli Lilly and Company**

“As a practical matter, there would appear to be no path to exercising ‘march-in’ rights without concomitantly executing an unauthorized taking of private sector rights...All that will come of the inappropriate exercise of ‘march-in’ rights is damage to America’s innovation engine, which has been forty years in the making and is the envy of the world.” – **Gillian Fenton, GlaxoSmithKline**

“March-in rights were meant to prohibit the licensee from keeping an invention from being practiced either by purposefully sitting on the invention to protect prior technology of the licensee, or for a company who cannot or will not produce a commercial product. Price is not a factor in March-in rights.” – **Robert N. Schmidt, Small Business Technology Council**

“NCBIO agrees that §401.6(a)(i) should clearly reaffirm that march-in rights should not be exercised by an agency on the basis of business decisions of a contractor regarding the pricing of commercial goods arising from the practical application of the invention.” – **Laura Gunter, NC Biosciences Organization**

“It is clear that misuse of Bayh-Dole march-in rights to control drug prices, will impede the creation of new drugs by discouraging university and medical school licensees from making the substantial additional investments necessary to take federally funded university-based research from the laboratory to the bedside. As Bayh-Dole also applies to all inventions arising from federally funded research with contractor organizations for any market sector, the private sector will be hesitant or unwilling to license federally funded inventions from universities, potentially inhibiting the progress of innovation, reducing public-private partnerships and damaging U.S. competitiveness, to the detriment of the economy, public health and safety.” – **Walter Copan, (formerly) National Institute of Standards and Technology**

“It is no exaggeration to say that the Bayh-Dole Act was one of the most significant and successful pieces of legislation enacted by Congress in the 20th Century, and there is no reason to attempt to subvert its true purpose by allowing its march-in provisions to be extended to impose price controls on products developed under its provisions.” – **David J. Glass, D. Glass Associates, Inc.**

“All of humanity benefits from the amazing advances in disease prevention and control that can result from talented and highly motivated University researchers under the Bayh-Dole regulations as they exist. The proposed regulations would hinder the continuation of this success.” – **Richard T. Miner**

“Since its inception, the Bayh-Dole Act has served as a framework for growth and a stimulus for the commercialization of discoveries that originate in Arizona. It is vital that the proposed regulations allow us to build on this successful track record.” – **Joan Koerber-Walker, Arizona Bioindustry Association, Inc.**

“NIST’s proposed revisions would generally reaffirm the longstanding understanding of the governments march-in rights under the University and Small Business Patent Procedures Act of 1980 – known as the Bayh-Dole Act. The Bayh-Dole Act is arguably one of the most inspired and influential pieces of legislation of the past half-century, driving innovative technologies, medical devices and drugs.” – **Kelvyn Cullimore, BioUtah**

“Adding the real or perceived risk of governmental march-in rights on the basis of price to the many obstacles to commercializing academic research results will significantly deter commercial investment and licensing.” – **Kim Rosenfield, Dartmouth College**

“As a technology transfer professional, I support the rulemaking clarification “the pricing of commercial goods and services arising from the practical application of the invention” should not be the basis for the exercise of march-in rights. Price should not be a factor in considering the exercise of march-in rights under the Bayh-Dole Act.” – **Doug Franz, Kenneth Karanja, Karen Ohlfest, University of Minnesota**

“Allowing march in rights to help govern pricing of a product is an inappropriate interpretation of that provision. If enacted it will seriously damage pharmaceutical research.” – **Mike Alder, Brigham Young University**

“I support the rulemaking clarification that “the pricing of commercial goods and services arising from the practical application of the invention” should not be the basis for the exercise of march-in rights. Price should not be a factor in considering the exercise of march-in rights under the Bayh-Dole Act.” – **Andrew J. Maas, Louisiana State University**

“The issue of drug pricing is complex, and we want to ensure that any effort to address consumer prices does not undermine the successful commercialization framework created by Bayh-Dole. NIST and other agencies should exercise care not to disrupt the knowledge transfer process that has been built over decades and has been emulated around the world.” – **Alexander E. Dreier, Yale University**

“Despite great promise in technologies discovered through government research, almost NONE of it is ready for market at that point. There is a tremendous amount of work still left to be done. March in rights and other punitive actions will simply take away the motivations of actors to do the derisking.” – **Bryan Ritchie, University of Notre Dame**

“I understand that some have expressed concerns about access to medicine in their comments on the March-in rulemaking. I also care about health access, and that’s why I oppose the abuse of march-in rights for reasons of price. Curing disease, treating patients, and providing access to medicines are core components of the mission of technology transfer. The goal of my profession is to bring ideas to market to make the world a better place. The misuse of march-in rights for price control would be ineffective, inappropriate, and counterproductive to public welfare.” – **RK Narayanan, Cold Spring Harbor Laboratory**

Endorsed by officials from the **University of California Davis, University of Georgia, University of Kentucky**

“These revised regulations will help the Bayh-Dole Act continue its 40-plus year mission of fostering increased economic growth, a higher standard of living and numerous high-paying jobs here in the United States.” – **Rick Huebsch, University of Minnesota**

“As a technology transfer professional at a public research university, I stand in support of the comments submitted by AUTM in opposition to the decision to inappropriately leverage the Dole Act for price regulation. Any such attempts would devastate the US innovation ecosystem, and create ripple effects on industries that engage with technology transfer offices domestically and internationally.” – **Elizabeth Sheckler, University of New Hampshire**

“Bringing nascent inventions to the market is inherently expensive, and the misuse of march-in rights for price control would have a chilling effect on private investment into these activities, and result in something counterproductive to public welfare.” – **Bruce Burgess, The University of Arizona**

“The reason BD works is because it brought clarity of rights and clarity of ownership to the innovation process at research institutions. Further clarification where there is confusion or misinterpretation of the statute, will be highly beneficial. For example, stating explicitly, once and for all, that march-in is not for price control is critical.” – **Fred Reinhart, UMass Amherst**

“The implementation of march-in rights with the purpose of serving as market price control will deter small businesses from investing in University innovations and will have the devastating effect of dampening the development of early-stage innovations, including those from underrepresented innovators striving to enter the entrepreneurial ecosystem.” – **Kevin H. Gardner, University of Louisville**

“The public-private partnership among the federal government, research universities and industry remains unparalleled and has resulted in the United States being the premier country for innovation and entrepreneurship. We are witnessing this success now as we become vaccinated against COVID 19 from vaccines resulting from this partnership. For over forty years, the Bayh-Dole Act (the “Act”) has provided support for this partnership by authorizing U.S. universities, nonprofit organizations, and small businesses to retain title to their federally funded intellectual property. There is no question that the Act is working.” – **Robin Rasor, Duke University**

“Changing Bayh-Dole to permit its use in price controls of commercialized products misaligns and removes all incentives to develop new solutions. It will ensure that the fruits of taxpayer-funded Federal research dollars wither on the vine, leading to tremendous waste and a fracturing of the existing innovation marketplace.” – **Marc Sedam, University of New Hampshire**

“As a technology transfer professional with more than 30 years experience, I strongly oppose the use of federal march-in rights to influence or control prices of commercial goods and services.” – **Richard Cox, University of Notre Dame**

“As with any critical asset, the Bayh-Dole Act needs regular maintenance to keep it sound and operating at peak performance so it can continue to deliver the important benefits both here at home and around the world as it has for over 40 years. As such, the University of Pittsburgh applauds NIST’s efforts to revise, update and clean-up the Bayh-Dole Act’s regulations.” – **University of Pittsburgh**

“Bayh-Dole should be used for its intended purpose: to encourage commercialization of Government-funded inventions. Any deviation from its purpose will discourage development of these inventions and will not solve any pricing issues. Bayh-Dole is not the problem of pricing and it is not the solution.” – **Katharine Ku, (formerly) Stanford University**

“We strongly support NIST’s clarification of march-in rights under Bayh-Dole such that ‘the pricing of commercial goods and services arising from the practical application of the invention’ should not be the basis for the exercise of march-in rights.” – **Richard W. Chylla, Michigan State University**